SILLS CUMMIS & GROSS P.C.
Jeffrey J. Greenbaum
Katherine M. Lieb
One Riverfront Plaza
Newark, New Jersey 07102
(973) 643-7000

PATTERSON BELKNAP WEBB & TYLER LLP
Adeel A. Mangi
Harry Sandick (*pro hac vice* forthcoming)
George LoBiondo
1133 Avenue of the Americas
New York, New York 10036
(212) 336-2000

Attorneys for Plaintiff
Johnson & Johnson Health Care Systems Inc.

UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

JOHNSON & JOHNSON HEALTH CARE SYSTEMS INC.,	:	Civil Action No.
Plaintiff,	:	Jury Trial Demanded
vs.	:	
SAVE ON SP, LLC,	:	**COMPLAINT**
Defendant.	:	

Plaintiff Johnson & Johnson Health Care Systems Inc. ("JJHCS"), having an address at 425 Hoes Lane, Piscataway, New Jersey 08854, for its Complaint against Defendant Save On SP, LLC, 611 Jamison Road, Elma, New York 14059 ("SaveOnSP"), alleges as follows:

PRELIMINARY STATEMENT

1. JJHCS brings this action to stop SaveOnSP's scheme to pilfer tens of millions of dollars from the financial support program that JJHCS provides for patients. The patient assistance that JJHCS provides is for *patients*—not for SaveOnSP or the health plans with

which it partners. By targeting and exhausting those funds for the benefit of its (and its partners') bottom line, SaveOnSP is increasing the cost of, and will ultimately render it untenable to provide, the assistance that patients desperately require. That will irreparably harm JJHCS and the patients it serves.

2. As a subsidiary of Johnson & Johnson, JJHCS provides funds to help commercially insured patients afford the costs of valuable and life-saving therapies. Those costs include the co-payments ("copays")[1] that insurance companies and private health plans ("payers") insist must be paid by patients to obtain their prescription drugs. Study after study has shown that many patients cannot afford such copays, and will be forced to forgo vital treatments unless help is provided to meet those obligations. JJHCS provides that support through its patient assistance program. However, with the deliberate intent to manipulate and thwart the purpose of JJHCS's program, SaveOnSP devised and implemented a scheme (the "SaveOnSP Program") to inflate and misappropriate the funding JJHCS provides for patients by interfering with the contractual relationship between JJHCS and patients.

3. SaveOnSP's scheme works by (i) circumventing statutory constraints on the level of copay costs that payers may require patients to pay for pharmaceuticals; (ii) inflating patients' copay costs in order to increase the funds extracted from JJHCS's patient assistance program and thereby reduce the portion of the drug cost that the payers otherwise would have to pay to the pharmacy; (iii) using this artificially inflated copay cost to coerce patients to enroll in a program run by SaveOnSP, in addition to, and in violation of the terms of, JJHCS's patient

[1] In this Complaint, the term "copay" is generally meant to encompass both an out-of-pocket fixed amount paid by the patient at the point of sale, as well as "co-insurance," or an out-of-pocket percentage of the cost of the product or service paid by the patient at the point of sale.

assistance program; and (iv) leveraging its illicit SaveOnSP Program to surreptitiously extract inflated amounts of patient assistance.

4. Through this artifice, SaveOnSP enriches the payers with which it partners by (a) reducing the amount they pay to pharmacists for each prescription in the SaveOnSP Program, and (b) increasing by a commensurate amount the costs to the JJHCS patient assistance program. In return for this exploitation and interference with JJHCS's program, the payers reward SaveOnSP with a 25% commission on their "savings."

5. As a result, the costs to JJHCS of providing patient support have exploded. SaveOnSP has caused JJHCS to pay at least $100 million more in copay assistance than it otherwise would have for a purpose JJHCS did not intend, depleting the support available for patients who cannot afford their rising copays. SaveOnSP knows this, and nonetheless has maliciously pursued this scheme to cause harm to JJHCS and the patients it supports while lining its own pockets.

Patient Out-of-Pocket Obligations & JJHCS's Patient Assistance

6. JJHCS does not and cannot control the price that a patient is asked to pay at a pharmacy when the patient goes to retrieve her or his medication. Rather, a patient's copay cost is determined and imposed by private payers and their affiliated entities. In recognition of the increasing costs that patients have faced at the pharmacy, since 2016, JJHCS has provided assistance to more than 2 million patients in order to help them defray their copay costs and more easily afford their life-saving and life-improving therapies.

7. The patient assistance program at issue here, the Janssen CarePath Program ("CarePath"), provides a portfolio of support services for patients using medications researched, developed, and marketed by the pharmaceutical companies of Johnson & Johnson, including Janssen Biotech Inc., Janssen Pharmaceuticals, Inc, Janssen Products, LP, and Actelion

Pharmaceuticals U.S., Inc. (collectively, "Janssen"). These medications include complex biologic treatments for various cancers and serious immunological conditions. Without JJHCS's assistance, many patients would be unable to afford their medications, potentially leading them to discontinue treatment, reducing their quality of life, and sometimes shortening their lives.

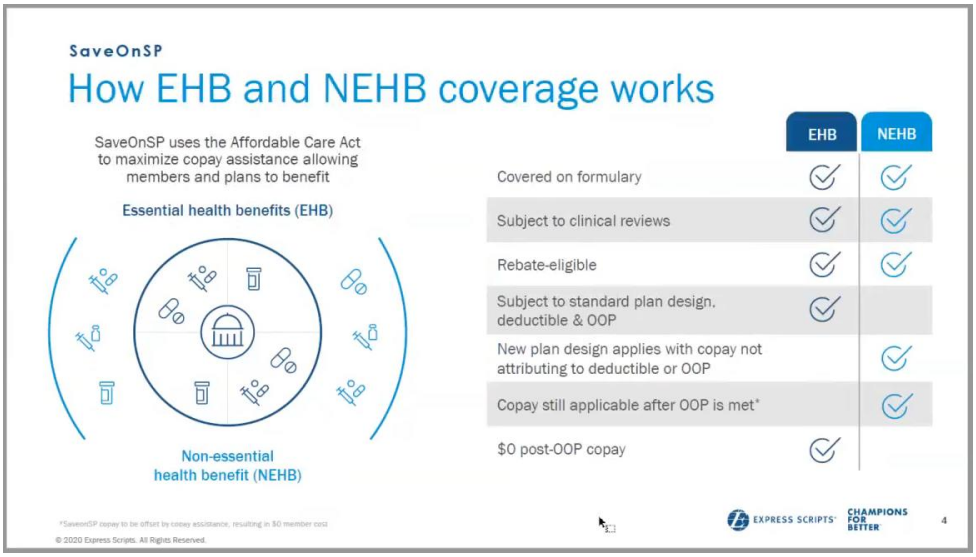
SaveOnSP's Actions Interfere with JJHCS's Patient Assistance

8. SaveOnSP knows that JJHCS funds patient assistance programs like CarePath to ease the burden on patients.[2] Nevertheless, SaveOnSP has planned and executed a scheme to exploit, interfere with, and ultimately render it untenable for JJHCS to continue the CarePath program by inflating patients' copay obligations to coerce patients to enroll in SaveOnSP's own program—in violation of CarePath's terms and conditions.

9. The SaveOnSP Program at the heart of SaveOnSP's scheme works by first changing the designation of Janssen's drugs—including live-saving cancer drugs and other critical medications—from "essential health benefits" to non-essential health benefits under the Affordable Care Act ("ACA"). Working in tandem with its payer partners, the SaveOnSP Program reclassifies the medications as non-essential ***without regard to patients' actual medical needs and solely for SaveOnSP's own profit motives***. Indeed, in a recorded presentation available online, a SaveOnSP Program representative admits: "The moment we reclassify these as non-essential we get to operate outside of those rules, which removes the limitations for how high we set the copay, it removes the requirement to apply copay assistance dollars to the max out-of-pocket. And that's what allows us to be the ***most lucrative*** in terms of driving savings for SaveOn." *See* David Cook, *IPBC and SaveonSP Training-20210216 1901-1*, VIMEO, at 23:35 (Feb 17, 2021), https://vimeo.com/513414094 (hereinafter, *SaveOnSP IPBC Video*).

[2] SaveOnSP is well-versed in JJHCS's program, as its founder is a former Johnson & Johnson employee, and its CEO is also a former Johnson & Johnson employee.

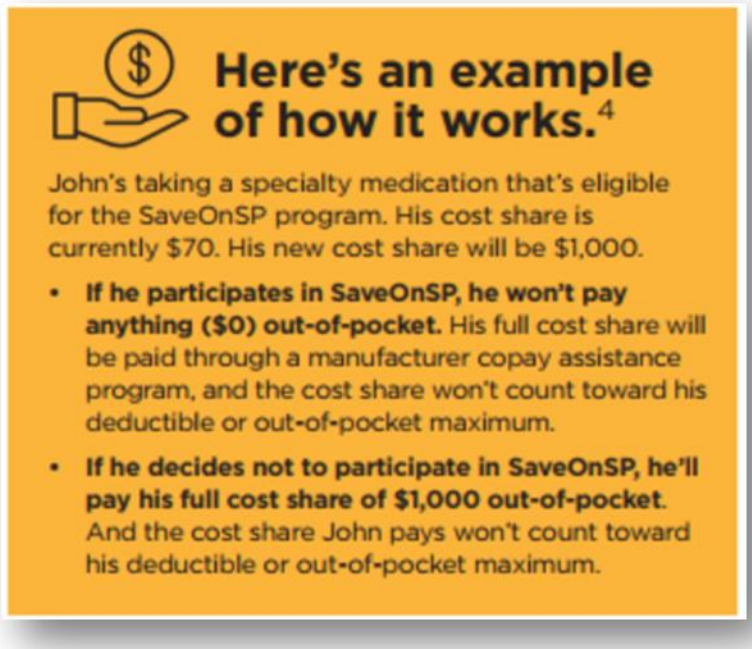
10. Once the SaveOnSP Program re-categorizes a drug as a non-essential health benefit, it is no longer subject to the ACA's annual out-of-pocket maximum that limits how much patients with private insurance can be required to pay for their medical care each year. The out-of-pocket maximum rule is meant to prevent patients from being forced to choose between vital medication and other necessities of life, such as food, clothing and housing. In direct contravention to this legislative intent, by reclassifying certain medications as non-essential health benefits, the SaveOnSP scheme allows the payer to continue to charge the patient inflated copay costs even where the patient has already satisfied their out-of-pocket maximum as indicated during the SaveOnSP Program presentation:



Id. at 24:00. In addition, after removing a given drug from the purview of the ACA's out-of-pocket maximum, the SaveOnSP Program increases the patient's copay for the given drug to an artificially high amount—often thousands of dollars per dose. As explained by the SaveOnSP Program representative, "[I]n order for us to capitalize on this copay assistance funding, ***we have to have that inflated copay upfront to bill to copay assistance.***" *Id.* at 49:26.

11. Further, in deciding which drugs to include in its program, SaveOnSP targets drugs that "***have the most lucrative copay assistance programs***," programs like CarePath. *Id.* at

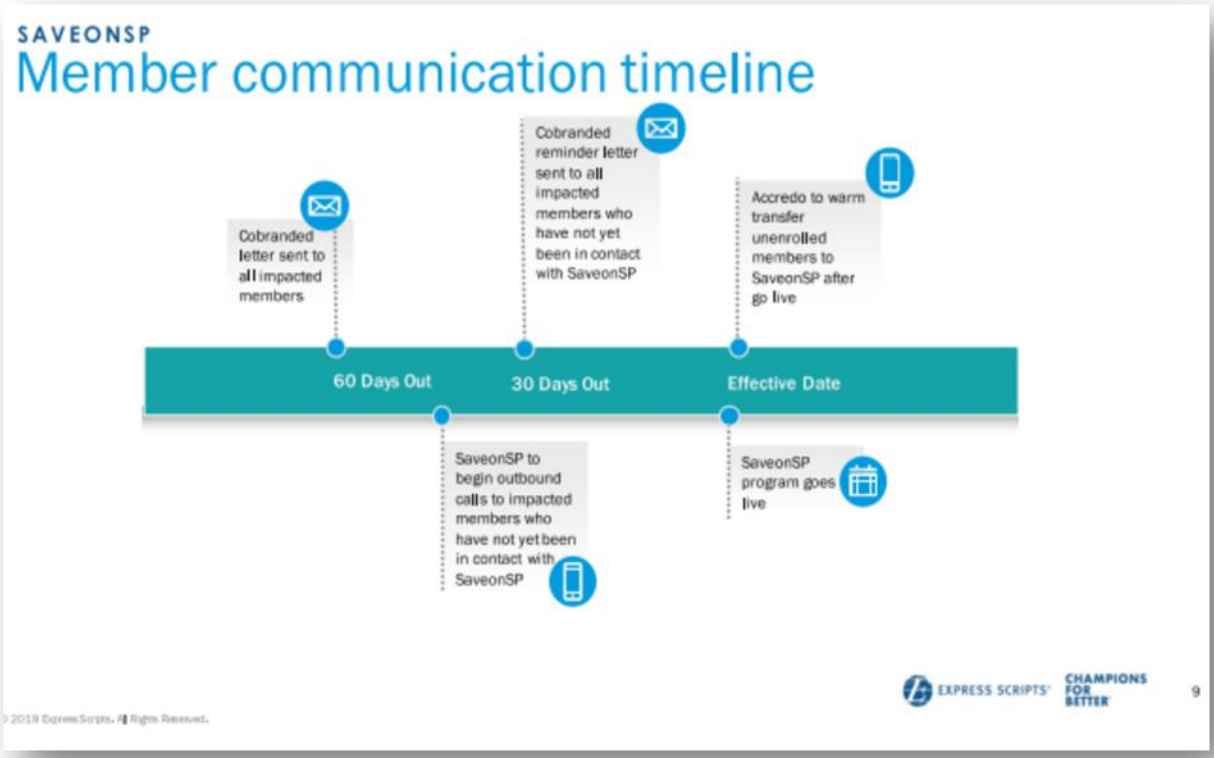
13:31.[3] Once it has included those drugs in the SaveOnSP Program and the drug's copay has been inflated, SaveOnSP then targets patients who take the drug, using the threat of an inflated copay to coerce them into enrolling in the SaveOnSP Program. Specifically, SaveOnSP tells each patient that unless she enrolls in the SaveOnSP Program, she will have to pay the inflated copay herself—and, making matters worse, the SaveOnSP Program will not count the thousands she pays toward her deductible or out-of-pocket maximum. SaveOnSP's offer is illustrated in marketing materials available online:



Pay $0 for Select Specialty Medications, CIGNA (Aug. 2021), https://hr.richmond.edu/benefits/insurance/medical-plans/pdf/SaveonSP.pdf (last visited Apr. 27, 2022).

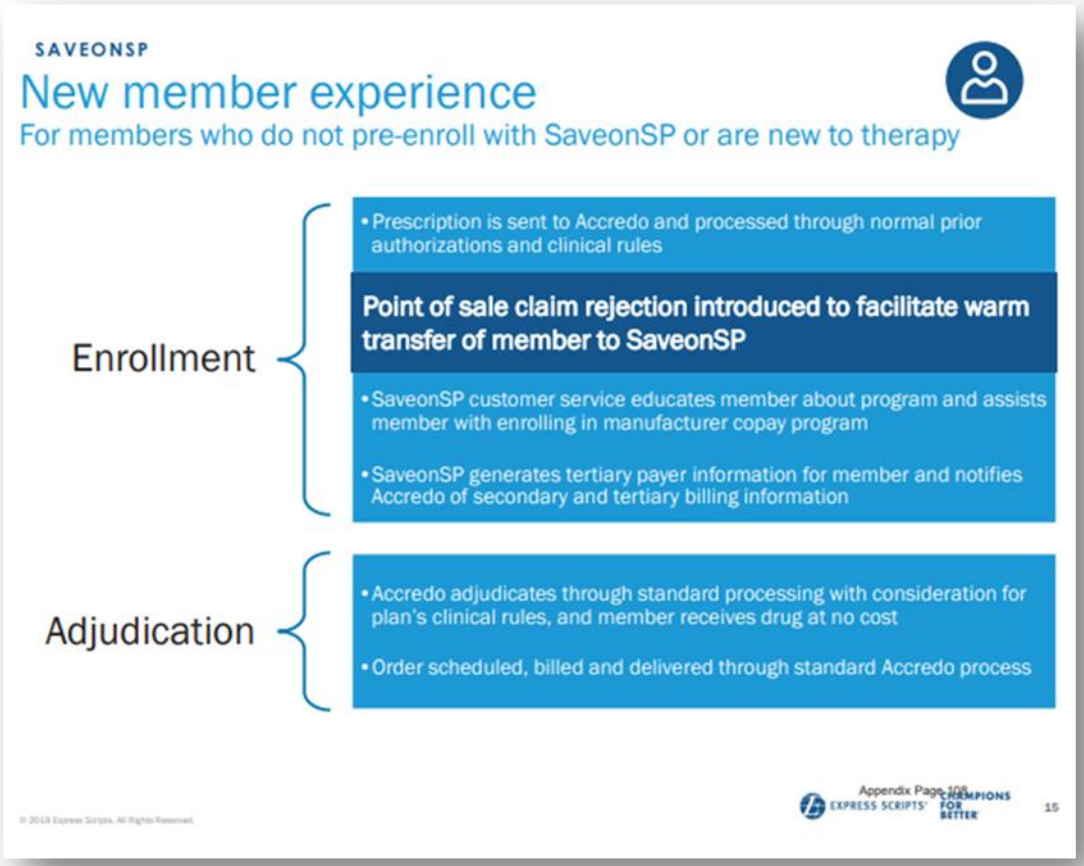
[3] Similarly, in the same recorded presentation, the SaveOnSP Program representative admits that the program works only if they are able to extract patient assistance: "In order for us to leverage the savings, the member has to actively enroll in copay assistance. ***That's where the savings comes from***." *SaveOnSP IPBC Video*, *supra* ¶ 9, at 49:27.

12. SaveOnSP engages in a concerted effort to communicate this coercive offer to patients, including through phone calls and letters. This outreach campaign is illustrated by a SaveOnSP Program slide deck available online:



Copay Assistance Program & Solutions, EXPRESS SCRIPTS, at 9 (2019), https://pebp.state.nv.us/wp-content/uploads/2020/03/7.-Combined-for-website.pdf.

13. SaveOnSP even goes so far as to enlist the help of the pharmacy to reject a patient's claim for their prescription medication at the point of sale—to tell the patient that insurance will not cover their prescription even though that medication is in fact covered—in order to get the patient on the phone with SaveOnSP so that a representative can pressure the patient to enroll in the SaveOnSP Program. This is highlighted in another SaveOnSP Program slide deck, which admits engineering a ***"[p]oint of sale claim rejection"*** to "facilitate warm transfer of member to SaveonSP":



Human Resources Committee Meeting, VILLAGE OF LINDENHURST ILLINOIS, at 69 (Mar. 11, 2021), https://www.lindenhurstil.org/egov/documents/1615238827_33717.pdf.

14. Of course, a choice between paying nothing for badly needed medication, or paying thousands of dollars for that medication out of pocket, is—for most patients—no choice at all. Indeed, many patients choose health plans precisely based on which plan purports to cover their necessary medications. Unsurprisingly, therefore, once SaveOnSP's offer is communicated to the patients, most are coerced into accepting: "[T]hat's often compelling enough for members to say, 'oh wait, I want my drugs for free.'" *SaveOnSP IPBC Video*, *supra* ¶ 9, at 46:25.

15. But while SaveOnSP is telling patients that their therapy will be "free" if they enroll in the SaveOnSP Program, what SaveOnSP is really doing is also enrolling them in

CarePath so that the cost of the artificially inflated copay is born by JJHCS and the entirety of the funds JJHCS makes available via patient assistance are drained. This is revealed when the SaveOnSP Program representative admits that patients may see an inflated copay on their "invoice paperwork," but "they will not be charged" that amount. *Id.* at 43:38; *see also, e.g.*, *Albuquerque Public Schools Summary of Benefits*, EXPRESS SCRIPTS, at 2 (2021), https://www.aps.edu/human-resources/benefits/documents/2021-summary-of-benefits/express-scripts-summary-of-benefits (stating that the cost of drugs for patients enrolled in SaveOnSP "will be reimbursed by the manufacturer").

16. Further, while SaveOnSP walks the patient through the process of enrolling in programs like CarePath, SaveOnSP does not tell patients that CarePath is already available to them without enrollment in the SaveOnSP Program, and already reduces patients' out-of-pocket costs to $10, $5, or even $0. In other words, the SaveOnSP Program exists not to benefit patients, but solely to wrongfully meet the payer's obligation to the patient using the cost support made available by JJHCS for SaveOnSP's own profit.

17. The SaveOnSP Program does not change the amount the pharmacist receives for a prescription. It decreases the portion that the payer pays of that amount, and increases the portion that the patient pays with patient assistance dollars. The payers' "savings" is actually the increased amount that payers withhold from pharmacists because the payers foist the obligation onto patients, who will use CarePath dollars to pay it. SaveOnSP then calculates the payers' "savings"—actually, the value the payer has gained by virtue of displacing its payment obligation to JJHCS—and charges the payer a fee of 25%.

SaveOnSP Disregards the Terms and Conditions of JJHCS's Program

18. SaveOnSP's scheme is expressly prohibited by the CarePath terms and conditions, which do not allow the program to be used in connection with any "other offer" like

the SaveOnSP Program. *See, e.g.*, DARZALEX® Savings Program (Sept. 2021), https://www.janssencarepath.com/sites/www.janssencarepath-v1.com/files/darzalex-faspro-yondelis-savings-program-overview.pdf.

19. The SaveOnSP Program is such an "offer." The SaveOnSP representative expressly refers to the SaveOnSP Program in her presentation as the "SaveOn ***offering***," *SaveOnSP IPBC Video*, *supra* ¶ 9, at 4:25; 27:31, and marketing materials state "That's why your plan ***offers*** a program called SaveOnSP, which can help lower your out-of-pocket costs to $0." *See Pay $0 for Select Specialty Medications*, *supra* ¶ 11 (emphasis added).

20. SaveOnSP is well aware of this prohibition on other offers because it monitors drug manufacturers' patient assistance terms and conditions. *See SaveOnSP IPBC Video*, *supra* ¶ 9, at 31:59. Nevertheless, SaveOnSP continues to coerce patients into signing up for and using the SaveOnSP Program—thereby inducing those patients to breach the terms and conditions of their CarePath agreement with JJHCS.

21. SaveOnSP's scheme harms patients in a number of ways, including by selecting drugs for coverage based upon a profit motive and not medical need; wrongfully engineering a denial of coverage at the point of sale to coerce patients to participate in the program; and not counting any of the funds spent on patients' medication towards their ACA maximum or deductible, thereby making their other healthcare needs more expensive.

22. Further, by imposing on JJHCS inflated costs that are not tethered to actual patient need, SaveOnSP's scheme ultimately will make it cost prohibitive for JJHCS to offer patient assistance. This result is aligned with the interest of payers, which have used a variety of

tactics—widely condemned by patient advocacy groups[4]—to deprive patients of the benefits of patient assistance. As payers well know, eliminating patient assistance will result in patients seeking less medicine than they otherwise need and would obtain, which would in turn increase payers' profits.[5]

23. SaveOnSP's scheme also harms JJHCS. SaveOnSP depletes the CarePath funds intended to help patients afford their Janssen medication, and causes JJHCS to pay out thousands of dollars more per patient in CarePath funds than it otherwise would pay, solely for SaveOnSP's and its partners' profit.

24. SaveOnSP concedes this misappropriation and diversion. Marketing materials for the SaveOnSP Program tout the "savings" that it generates for payers. For example, one health plan projected $600,000 in annual "savings" from implementing the SaveOnSP Program. *See SaveOnSP for Specialty Medications*, VALLEY CENTER PAUMA UNIFIED SCHOOL DISTRICT, https://vcpusd.learning.powerschool.com/c/1720900/file/show/159819292; *see also Copay Assistance Program & Solutions*, *supra* ¶ 12, at 8 (projecting $1.9

[4] For instance, the "All Copays Count Coalition," made up of more than 60 groups representing patients with serious and chronic health conditions, has engaged in a concerted effort to stop payer use of "accumulators," programs that identify patient assistance funds and refuse to count them toward the patient's deductible or out-of-pocket maximum. *See New Insurance Policies Are Targeting Vulnerable Patients with High Copays*, NAT'L HEMOPHILIA FOUND., https://www.hemophilia.org/advocacy/federal-priorities/make-all-copays-count#ACCC (last visited Apr. 27, 2022). Accumulators and the harms they cause to patients are discussed in greater detail in Section III, *infra*.

[5] Certain payers have argued that copay assistance programs artificially increase payers' costs by "incentivizing patients to take brand-name drugs instead of cheaper bioequivalent generics" or even by incentivizing patients to take medications they do not require. *See, e.g.*, Tomas J. Philipson et al., *The Patient Impact of Manufacturing Copay Assistance in an Era of Rising Out-of-Pocket*, UNIV. CHI. (Dec. 2021), at 18, https://cpb-us-w2.wpmucdn.com/voices.uchicago.edu/dist/d/3128/files/2021/12/2021_12_15-Copay-Assistance-Final-Draft-Clean.pdf (last visited Apr. 27, 2022). Beyond the absurdity of suggesting that copay assistance causes a patient suffering from cancer to take a cancer therapy they do not require, this argument overlooks that copay assistance is often used for specialty drugs without a generic substitute. *Id.*; *see infra* ¶ 34.

million in "savings" in 2020 for one health plan from implementing SaveOnSP); *Copay Assistance Strategy Reduces Financial Burdens for Plans and Patients*, EVERNORTH (Oct. 7, 2021), https://www.evernorth.com/articles/reduce-costs-for-health-care-plans-with-copay-program-assistance (advertising that "[i]n 2020, plans that participated in these copay assistance solutions [like the SaveOnSP Program] experienced a specialty [drug cost] trend of -7.2%, while nonparticipating plans experienced an 8.7% specialty [drug cost] trend."). But in fact, these "savings" are simply diverted CarePath funds that were intended to benefit patients, not payers.

25. Patient assistance does not exist so that SaveOnSP can enrich payers further while taking a cut itself. Indeed, payers already negotiate enormous price concessions from manufacturers, including rebates that manufacturers pay when a patient fills a prescription. In 2021 alone, Janssen paid more than $8 billion in rebates, discounts, and fees to commercial insurers and pharmacy benefit managers. *See The 2021 Janssen U.S. Transparency Report*, at 6, https://2021jtr.prod.cmc.jnj-secondary.psdops.com/_document/the-2021-janssen-u-s-transparency-report?id=00000180-0108-dccf-a981-a52ec8300000 (last visited Apr. 27, 2022); *see also Form 10-K*, CIGNA CORP., at 37 (Feb. 24, 2022), https://investors.cigna.com/financials/sec-filings/default.aspx ("We maintain relationships with numerous pharmaceutical manufacturers, which provide us with, among other things: . . . discounts, in the form of rebates, for drug utilization."). SaveOnSP acknowledges that these payer rebates are a "completely different set of funds" from *patient* assistance—which, SaveOnSP further acknowledges, is made available pursuant to "an agreement between the member and the manufacturer." *SaveOnSP IPBC Video*, *supra* ¶ 9, at 24:32-24:50. By tortiously interfering with that agreement between JJHCS and patients, SaveOnSP wrongfully enables payers to "double-dip" into both manufacturer rebates and copay assistance.

26. SaveOnSP should not be permitted to profiteer on the backs of patients by exploiting JJHCS's patient assistance. SaveOnSP should therefore be enjoined from including Janssen drugs in the SaveOnSP Program, and should be ordered to compensate JJHCS for the funds it caused to be wrongfully extracted from CarePath.

THE PARTIES

27. Plaintiff JJHCS is a corporation organized under the laws of the State of New Jersey, with its principal place of business at 425 Hoes Lane, Piscataway, New Jersey 08854. JJHCS is a subsidiary of Johnson & Johnson, and administers CarePath for the benefit of patients who are prescribed medications marketed by other Johnson & Johnson entities that are not fully paid for by private insurance.

28. Defendant SaveOnSP is a limited liability company organized under the laws of the State of New York, with its principal place of business at 611 Jamison Road, Elma, New York 14059. SaveOnSP advertises and administers its program (the "SaveOnSP Program") in partnership with pharmacy benefits manager Express Scripts, Inc. ("Express Scripts") and specialty pharmacy Accredo Health Group, Inc. ("Accredo"). SaveOnSP has operations, including a call center, in Buffalo, New York. It also makes its client payers sign a joinder agreement governed by the laws of New York, and, on information and belief, accepts payments for its services in New York. Upon information and belief, none of the members of SaveOnSP are citizens of New Jersey.

JURISDICTION AND VENUE

29. This Court has personal jurisdiction over SaveOnSP because SaveOnSP has sufficient minimum contacts with New Jersey so as to render the exercise of jurisdiction by this Court permissible under traditional notions of fair play and substantial justice. SaveOnSP actively implements the SaveOnSP Program in New Jersey, including by offering the SaveOnSP

Program to New Jersey payers, and by inducing New Jersey patients to enroll in the SaveOnSP Program.

30. Venue is proper pursuant to 28 U.S.C. § 1391(b) because "a substantial part of the events or omissions giving rise to the claim" occurred in this judicial district, including SaveOnSP's offering of the SaveOnSP Program to New Jersey payers, New Jersey patients' enrollment in the SaveOnSP Program, violation of CarePath's terms and conditions, and JJHCS's injury as a result of SaveOnSP's wrongful acts.

31. This Court has subject matter jurisdiction pursuant to 28 U.S.C. § 1332 because the amount in controversy in the present action exceeds the sum or value of seventy-five thousand dollars ($75,000.00), exclusive of interests and costs, and complete diversity of citizenship between the parties exists because JJHCS is a citizen of New Jersey, while SaveOnSP's members are not.

FACTUAL ALLEGATIONS

I. The Pharmaceuticals for which JJHCS Offers Support Have Improved and Saved the Lives of Countless Patients

32. The pharmaceuticals for which JJHCS offers support are essential to patients' health and, in some cases, survival. These pharmaceuticals include treatments for various forms of cancer (for example, DARZALEX®, ERLEADA®), pulmonary arterial hypertension (for example, OPSUMIT®, TRACLEER®, UPTRAVI®), and various autoimmune disorders (for example, REMICADE®, STELARA®, TREMFYA®).

33. A significant percentage of CarePath funds are provided for treatments known as "biologics," which are medications developed from living materials, usually cells, and which have complex molecular structures that are not easily definable. This complexity is in contrast to more conventional medications, which tend to be chemically synthesized and have

simpler molecular structures. Because of this complexity, biologic therapies cannot be precisely copied, meaning that there are no "generic" versions of these molecules that can be substituted for branded products without a physician's prescription, as there are for simpler chemical compounds.[6] *See also* Tomas J. Philipson et al., *The Patient Impact of Manufacturing Copay Assistance in an Era of Rising Out-of-Pocket*, UNIV. CHI. (Dec. 2021), at 18, https://cpb-us-w2.wpmucdn.com/voices.uchicago.edu/dist/d/3128/files/2021/12/2021_12_15-Copay-Assistance-Final-Draft-Clean.pdf (last visited Apr. 27, 2022) (noting that "copay cards are used primarily for brand drugs without a generic substitute").

34. Biologics remain at the cutting edge of medical science, and they are often used to treat life-altering medical conditions for which no other treatments are available. Janssen's biologic treatments are essential to the health of patients in a variety of important therapeutic areas, including immunology, oncology, and pulmonary hypertension. For example, STELARA® is an immunology biologic used to treat hundreds of thousands of patients in the United States for Crohn's disease, ulcerative colitis, and other chronic health conditions. TREMFYA® is an immunology biologic used to treat joint pain, stiffness, and swelling caused by psoriatic arthritis, as well as painful patches on the skin caused by moderate-to-severe plaque psoriasis. DARZALEX® is an oncology biologic used to treat multiple myeloma, a form of cancer that targets plasma cells found in bone marrow. For these and most of Janssen's other

[6] There are "biosimilar" versions of certain biologics on the market. *See* Biosimilar and Interchangeable Products, FDA, https://www.fda.gov/drugs/biosimilars/biosimilar-and-interchangeable-products (last visited Apr. 27, 2022) ("A biosimilar is a biological product that is highly similar to and has no clinically meaningful differences from an existing FDA-approved reference product."). A biosimilar may also qualify for a designation by the FDA that it is "interchangeable" with the original branded product. Currently, there are no FDA-approved interchangeable biosimilars for any Janssen product.

biologic therapies, there are currently no FDA-approved "biosimilar" versions of the same molecule on the market.

35. Developing these biologics is an expensive and risky venture for Janssen and other pharmaceutical manufacturers. In order to produce safe and effective biologic treatments, Janssen makes enormous investments in research and development. Even so, only 1 in 5,000 drug candidates makes it from discovery to market, and even for successful drugs, the entire process takes approximately 10 to 12 years. Further adding to the expense, biologics require rigorous quality control during the manufacturing process, as they are sensitive to even minute changes in raw materials and can be compromised by changes in temperature or microbial contamination. Manufacturing biologics thus requires specialized manufacturing equipment and facilities. Without manufacturers like Janssen who are willing to take on these risks and costs, innovative and life-saving biologic treatments would not be available to patients suffering from a range of diseases.

II. CarePath Offers Patients Thousands of Dollars in Financial Assistance to Help Defray Out-of-Pocket Costs that Limit Access to Medication

36. Patients with private commercial health insurance, especially those with acute complex medical conditions, are increasingly subject to higher and higher cost-sharing obligations imposed by their insurers, making it harder for patients to access medications prescribed by their doctors.

37. Health insurance plan sponsors do not typically determine these obligations alone. Rather, they contract with entities known as "Pharmacy Benefits Managers" or "PBMs." PBMs are companies that manage prescription drug benefits on behalf of health insurance plans. They often serve as middlemen with an aim towards increasing insurers' and their own profits by

determining which drugs a plan will cover and to what extent they will be covered. Express Scripts, Inc. is a PBM.

38. PBMs are also often part of even larger, vertically integrated organizations that offer other services in the health insurance field. For example, such organizations may offer health insurance themselves or operate specialty pharmacies, i.e., pharmacies that dispense complex pharmaceuticals like biologics that require special handling and care. Express Scripts, for example, is itself a subsidiary of the major insurance company Cigna.

39. In their role as middlemen, PBMs have presided over the rise of high cost-sharing insurance plans, which feature higher than usual deductibles, copays, and co-insurance. In essence, these plans pressure patients to limit their medical expenses by covering the full cost only after significant contributions by the patients. For instance, when a patient's health plan has a deductible, he or she must pay the entire price for the drug until the deductible threshold is met. Only once the deductible is met will the payer help the patient pay for the drug, at which point the patient may still pay either a fixed amount known as a copay, or a percentage of the drug's price, known as co-insurance.

40. Health plans with deductibles for prescription medications are becoming more common. Between 2012 and 2017, the share of employer-sponsored health plans requiring patients to meet a deductible for prescription medications rose from 23% to 52%. *See Faced with High Cost Sharing for Brand Medicines, Commercially Insured Patients with Chronic Conditions Increasingly Use Manufacturer Cost-Sharing Assistance*, PHRMA, at 3 (Jan. 29, 2021), https://phrma.org/-/media/Project/PhRMA/PhRMA-Org/PhRMA-Org/PDF/D-F/Faced-with-High-Cost-Sharing-for-Brand-Medicines.pdf.

41. These high-cost sharing models have been found to discourage patients from filling their prescriptions and can lead to abandonment of treatment. *See, e.g.*, Katie Devane et al., *Patient Affordability Part Two: Implications for Patient Behavior & Therapy Consumption*, IQVIA (2018), https://www.iqvia.com/locations/united-states/library/case-studies/patient-affordability-part-two (finding that 52% of new patients with an out-of-pocket cost of $125 to $250 abandoned treatment, and 69% of new patients with an out-of-pocket cost of $250.01 abandoned treatment); Jalpa A. Doshi et al., *Association of Patient Out-of-Pocket Costs With Prescription Abandonment and Delay in Fills of Novel Oral Anticancer Agents*, JOURNAL OF CLINICAL ONCOLOGY (Dec. 20 2017), https://ascopubs.org/doi/abs/10.1200/JCO.2017.74.5091 (finding that abandonment of oral cancer treatment increased from 10% for patients with a $10 out-of-pocket cost or less to 31.7% for patients with a $100.01 to $500 out-of-pocket cost, 41% for patients with a $500.01 to $2,000 out-of-pocket cost, and 49.4% for patients with an out-of-pocket cost exceeding $2,000); Michael T. Eaddy, *How Patient Cost-Sharing Trends Affect Adherence and Outcomes*, PHARMACY & THERAPEUTICS (Jan. 2012), https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3278192/ (conducting literature review of 160 articles from January 1974 to May 2008 and finding that "85% showed that an increasing patient share of medication costs was significantly associated with a decrease in adherence").

42. Patient abandonment of prescribed medication is a serious, potentially fatal problem. It is associated with "poor therapeutic outcomes, progression of disease, and an estimated burden of billions per year in avoidable direct health care costs." Aurel O. Iuga & Maura J. McGuire, *Adherence and Healthcare Costs*, 7 RISK MGMT. HEALTHCARE POLICY 35 (Feb. 2014), https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3934668/.

43. In order to limit the negative effects of inflated out-of-pocket costs, the ACA places annual limits on the amount of out-of-pocket costs a payer can force a patient to pay for so-called "essential health benefits," which includes many prescription drugs. *See* 45 C.F.R. § 156.130(a). For example, the annual ACA out-of-pocket maximum for the 2022 plan year is $8,700 for an individual and $17,400 for a family. *See Out-of-Pocket Maximum/Limit*, HEALTHCARE.GOV, https://www.healthcare.gov/glossary/out-of-pocket-maximum-limit/ (last visited Apr. 27, 2022). Nevertheless, that threshold is high enough that many patients would still be unable to afford the costs of their medication without help.

44. Thus, in the face of these ever-increasing cost-share obligations, financial assistance like that provided by JJHCS has become an important safety net helping patients pay for necessary medications. *See The Patient Impact of Manufacturing Copay Assistance in an Era of Rising Out-of-Pocket*, *supra* ¶ 33, at 2 (explaining that "[m]anufacturer copay assistance is a tool to ensure drug affordability in response to higher list prices and shifts in benefit design that put more out-of-pocket burden on commercial patients" and that "[w]ithout copay assistance, . . . OOP spending would have increased 3.4 percent from 2015 to 2019, growing from $46.6 billion to $48.2 billion. However, due to the growing use of copay cards in response to growing OOP exposure, patients faced a lower OOP burden, so actual OOP spending paid by patients was lower and decreased 6.3 percent, from an estimated $38.6 billion to $36.2 billion"). Such financial assistance is offered in the form of programs providing patients with coupons or a card that they can then use when purchasing their prescription medications.

45. Patients with chronic illnesses are increasingly reliant on patient assistance to afford their medications. For example, in 2019, 32% of patients filling brand-name oncology medicines used patient assistance, as did 45% of patients filling brand-name depression

medicines, 55% of patients filling brand-name HIV medicines, and 70% of patients filling brand-name multiple sclerosis medicines. *Faced with High Cost Sharing for Brand Medicines, Commercially Insured Patients with Chronic Conditions Increasingly Use Manufacturer Cost-Sharing Assistance*, *supra* ¶ 40, at 6. Without patient assistance, average patient out-of-pocket costs for brand medicines would have been 225% to 1,096% higher in 2019, depending on the illness category. *Id.* at 7; *see also The Patient Impact of Manufacturing Copay Assistance in an Era of Rising Out-of-Pocket*, *supra* ¶ 33, at 2 (noting that "[c]opay cards are even more important to offset high-cost exposures for patients taking specialty drugs as 50 percent of patients taking a specialty brand drug use copay cards versus 33 percent of patients on traditional brand drugs. The savings from copay cards lead patients to have similar final OOP costs between specialty drugs and traditional drugs due to an average savings of $1,548 for specialty drugs and only $414 for traditional drugs"). On average, patient assistance helped patients taking brand HIV and oncology medicines with more than $1,600 in costs, and patients taking brand MS medicines with more than $2,200 in costs. *See Faced with High Cost Sharing for Brand Medicines, Commercially Insured Patients with Chronic Conditions Increasingly Use Manufacturer Cost-Sharing Assistance*, *supra* ¶ 40, at 7.

46. These savings are critical to improving and saving the lives of patients who have private insurance without causing them to choose between treatment and other necessary expenditures, such as food, clothing and housing. Multiple studies have found that when manufacturers help patients pay their out-of-pocket costs, patients are more likely to obtain their medication and adhere to their treatment regimens. *See, e.g.*, Anna Hung et al., *Impact of Financial Medication Assistance on Medication Adherence: A Systematic Review*, 27 J. MGMT. CARE SPECIALTY PHARM. 924 (July 2021); *The Patient Impact of Manufacturing Copay*

Assistance in an Era of Rising Out-of-Pocket, *supra* ¶ 33, at 4 ("[A]ffordability offered by copay assistance has resulted in increased utilization of needed drugs. . . . Copay cards lower the out-of-pocket costs for patients leading them to increase their utilization by 4.8 to 16.7 percent."); Matthew Daubresse et al., *Effect of Prescription Drug Coupons on Statin Utilization and Expenditures: A Retrospective Cohort Study*, 37 PHARMACOTHERAPY 12 (Jan. 2017), https://accpjournals.onlinelibrary.wiley.com/doi/10.1002/phar.1802.

47. CarePath helps patients afford out-of-pocket costs for 44 Janssen drugs. For most of these drugs, CarePath offers patients up to $20,000 in assistance towards their out-of-pocket costs per calendar year. This assistance is meant not only to help patients afford their out-of-pocket costs for medications, but also to help patients meet their deductible and ACA out-of-pocket maximums, thereby allowing patients to more easily afford their healthcare overall.

48. To be eligible for CarePath, patients must meet certain criteria set forth in CarePath's terms and conditions. Relevant here, patients using CarePath must be enrolled in commercial or private health insurance (not, for example, Medicare). For some drugs, patients agree to pay $5 or $10 themselves at the point of sale. Also, the terms state that CarePath "may not be used with any other coupon, discount, prescription savings card, free trial, or ***other offer***." (emphasis added). And patients agree that they "meet the program requirements every time [they] use the program." *See, e.g.*, DARZALEX® Savings Program, *supra* ¶ 18.

49. Patients may enroll in CarePath online using the MyJanssenCarePath.com website, by phone, or via mail or fax by filling out and sending an enrollment form. Once enrolled, patients receive a card they can then use at the point of sale to cover the out-of-pocket costs for their prescription medication minus the $5 or $10 they agreed to pay themselves.

III. SaveOnSP Employs a Scheme to Drain Patient Assistance Program Funds for Its Own Benefit and the Benefit of Its Partners

50. Although programs like CarePath are meant to help patients, payers and PBMs have devised a set of evolving schemes designed to capture the benefit of patient assistance funds.[7] The scheme at issue in this lawsuit represents the latest in this line, and is administrated by SaveOnSP.

51. SaveOnSP's business model is to drain patient assistance from programs like CarePath by increasing patient out-of-pocket costs in a manner that serves no end other than to maximize profits for SaveOnSP and its partners. SaveOnSP's compensation is based on a contingency fee; it is paid a percentage based on the amount of patient assistance it is able to extract from manufacturer programs like CarePath. In partnership with PBM Express Scripts and specialty pharmacy Accredo, SaveOnSP markets and sells its program to payers, and then induces patients to enroll.

52. The contours of the SaveOnSP Program, and the partnership between Express Scripts and SaveOnSP in particular, are governed by a non-public "Master Program

[7] For instance, for years and continuing today, various payers and PBMs have employed programs known as "accumulators." These programs work by identifying and accepting manufacturer copay assistance, but refusing to count it toward the patient's deductible or out-of-pocket maximum. Adam J. Fein, *Copay Maximizers Are Displacing Accumulators—But CMS Ignores How Payers Leverage Patient Support*, DRUG CHANNELS (May 19, 2020), https://www.drugchannels.net/2020/05/copay-maximizers-are-displacing.html. Because none of the patient assistance counts towards the patient's deductible or out-of-pocket maximum, the scheme delays or prevents the patient from meeting those thresholds, and patient assistance that would normally be sufficient to last all year gets completely used up much earlier. *Id.* This leads to serious patient harm, as the patient will eventually go to fill a prescription and be shocked to learn that the patient assistance has run out and that the deductible and out-of-pocket maximum still have not been met—meaning he or she will have to pay the full list price or leave empty handed. *Id.* Patients often simply cannot afford to pay such costs without assistance, leading many patients to discontinue their treatment. The harm caused by such programs has led 11 states to ban them. Joseph Cantrell, *State Legislative Issues to Watch in 2022*, THE RHEUMATOLOGIST (Jan. 7, 2022), https://www.the-rheumatologist.org/article/state-legislative-issues-to-watch-in-2022/.

Agreement, effective November 13, 2017." *See* Res. 20-660, CITY OF JERSEY CITY, Exhibit B (Sept. 10, 2020), https://cityofjerseycity.civicweb.net/document/33785/Express%20Scripts%20-%20SaveOn%20Program.pdf. Further, SaveOnSP's public-facing website provides limited information about how its program functions. *See Frequently Asked Questions*, SAVEONSP, https://www.saveonsp.com/employers/ (last visited Apr. 27, 2022).

53. Nevertheless, SaveOnSP's modus operandi is revealed in a video posted online showing a SaveOnSP Program presentation to an Illinois-based health insurance plan sponsor. *See SaveOnSP IPBC Video, supra* ¶ 9. In the presentation, the representative admits that the SaveOnSP Program works by designating drugs covered under the health plan as non-essential health benefits: "for a number of drugs, we can carve them out and create a different benefit design, where we designate these drugs as non-essential." *Id.* at 5:30.

54. This designation prevents any money paid towards the drug from applying to the ACA's annual limit. *Id.* at 7:23 ("[W]e're not gonna allow [patient assistance] to hit [the patient's] max out-of-pocket."). This is because the ACA's annual limit applies only to "essential health benefits." *See* 45 C.F.R. § 155.20 (defining "cost sharing" so that the annual out-of-pocket maximum applies only to "any expenditure required by or on behalf of an enrollee with respect to ***essential health benefits***" (emphasis added)).

55. As is clear from the presentation, there is no legitimate medical reason for applying the designation, as the drugs are plainly essential for the health and well-being of many patients. Rather, SaveOnSP uses the designation to extract as much money from patient assistance as possible: "***The moment we reclassify these as non-essential we get to operate outside of those rules, which removes the limitations for how high we set the copay***, it removes the requirement to apply copay assistance dollars to the max out-of-pocket. And that's what

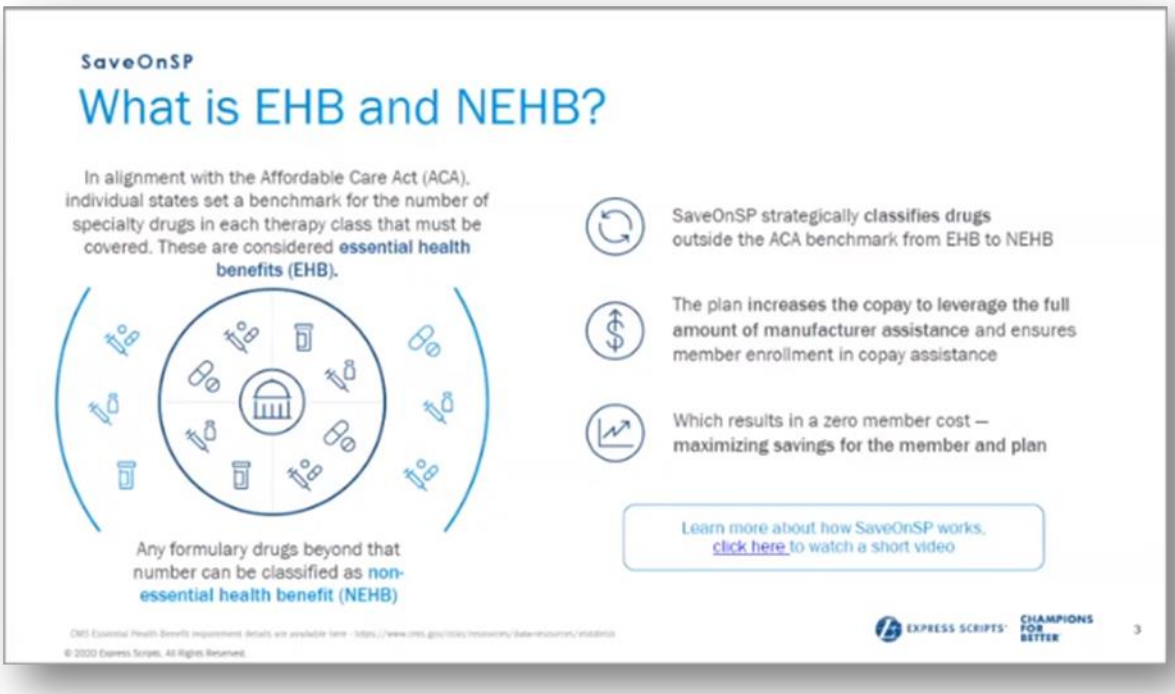
allows us to be ***the most lucrative*** in terms of driving savings for SaveOn." *SaveOnSP IPBC Video*, *supra* ¶ 9, at 23:35.

56. This "inflated" copay cost is essential to the SaveOnSP Program's mission of siphoning off patient assistance funds from programs like CarePath: "in order for us to capitalize on this copay assistance funding, ***we have to have that inflated copay upfront to bill to copay assistance***." *Id.* at 19:01. For example, the representative explains, if the amount of assistance per fill is $6,600: "we would literally set the patient copay to $6,600, and you would save that amount on every fill." *Id.* at 6:11. To be clear, the "you" in this presentation is the payer—not the patient.

57. SaveOnSP's method exploits what it perceives as a loophole in the ACA. To cover the required number of prescription drugs mandated by the ACA, a payer must identify as "essential" the greater of "(i) One drug in every United States Pharmacopeia (USP) category and class" or "(ii) The same number of prescription drugs in each category and class as the EHB-benchmark plan."[8] 45 C.F.R. § 156.122(a)(1); *see also* 42 U.S.C. § 18022(b)(1) (specifying that the Secretary of HHS shall "define the essential health benefits" including, *inter alia*, "prescription drugs").

[8] An "EHB-benchmark plan" is a "standardized set of essential health benefits that must be met by a" payer. 45 C.F.R. § 156.20. Each state typically selects the parameters for their own EHB-benchmark plan. 45 C.F.R. § 156.100.

58. Because the regulation requires that payers provide "the same number" of prescription drugs in each category or class as the specified benchmark plans, SaveOnSP takes the view that payers may de-designate drugs covered beyond that number. This view is reflected in a slide accompanying the recorded presentation:



SaveOnSP IPBC Video, *supra* ¶ 9, at 9:30.

59. The Centers for Medicare & Medicaid Services ("CMS") has stated that if a payer "is covering drugs beyond the number of drugs covered by the [EHB] benchmark, all of these drugs are EHB" and cost sharing paid for drugs properly classed as EHB "must count toward the annual limitation on cost sharing." *See Patient Protection and Affordable Care Act*, 80 Fed. Reg. 10749, 10817 (Feb. 27, 2015) (codified at 45 C.F.R. pts. 144, 147, 153, 154, 155, 156 and 158). SaveOnSP's Program defies this admonition. Instead, SaveOnSP and its partners designate covered drugs—including life-saving oncology, pulmonary arterial hypertension, and

immunology drugs—as non-essential health benefits so that it can inflate patient copay obligations.

60. Once the copay cost is inflated, SaveOnSP can coerce the patient into enrolling in its Program (and consequently in manufacturer programs) by telling them that they will either pay $0 per prescription if they enroll, or will have to pay the inflated copay cost—potentially in the thousands of dollars—themselves if they do not: "Meaning if you don't participate in this program, your copay or your responsibility will be [for example] $1,000. And because it's not part of your existing benefit design, that $1,000 is not applicable to your max out-of-pocket. And that's often compelling enough for members to say, 'oh wait, I want my drugs for free.'" *SaveOnSP IPBC Video*, *supra* ¶ 9, at 46:10. Because most patients cannot afford such costs, they are essentially forced into acceding to SaveOnSP's offer.

61. To communicate this coercive offer to patients, SaveOnSP first engages in outreach. The representative explains that once the payer signs the contracts to use its program, "there is a standard member letter that we have that can be co-branded" that is sent to patients in the first 30 days, "and it's our goal to outreach to every one of these members before the program ever goes live." *Id.* at 33:27; 34:04. The representative explains further that "at 30 days out, if we're unsuccessful in reaching those members, we send a reminder letter and again, another phone call campaign with attempts to try and get contact with that member and get them enrolled." *Id.* at 34:25.

62. On average, however, only 55% to 65% of the payer's membership typically gets enrolled by the date that the program goes live. *Id.* at 34:50. At this point, SaveOnSP leverages its partnership with the specialty pharmacy Accredo to facilitate patient enrollment. As the specialty pharmacy designated by the payers to administer the drug benefit plan, Accredo

steers the patients to SaveOnSP. In the words of the SaveOnSP Program representative, "our Accredo advocates, once the claim is processed, will receive a prompt to alert them that this is a SaveOn drug, and they have some scripting that says, 'We have an opportunity for you to participate in a program which allows you to get your drug for free. I need to connect you to SaveOn now.' And at that point in time, they 'warm transfer'[9] the member to SaveOn." *Id.* at 34:14.

63. As illustrated in paragraph 13 above, adding to the pressure placed on patients, Accredo actually ***rejects*** the patient's claim for their prescription medication at the point of sale in order to transfer them to SaveOnSP, even though that medication is covered by the patient's insurance. *Human Resources Committee Meeting*, *supra* ¶ 13, at 69.

64. Once the patient agrees to enroll in its program, SaveOnSP helps the patient enroll in manufacturer patient assistance programs. The representative explains that SaveOnSP "can help facilitate with the member on the phone" to guide them through online enrollment, or if enrollment is by phone, can advise patients "as how to respond to the questions that they're being asked as part of enrollment." *SaveOnSP IPBC Video*, *supra* ¶ 9, at 16:08; 16:38.

65. SaveOnSP inserts itself in this process even though it knows that the enrollment in its program violates the express terms and conditions of the CarePath agreement that prohibit the patient from combining CarePath with the SaveOnSP Program. SaveOnSP recognizes that the CarePath relationship "is an agreement between the patient and copay assistance through the manufacturer," but nevertheless involves itself because "in order for us to leverage the savings, the member has to actively enroll in copay assistance. ***That's where the***

[9] A "warm transfer" is "a telecommunications mechanism in which the person answering the call facilitates transfer to a third party, announces the caller and issue and remains engaged as necessary to provide assistance." *Warm Transfer Definition*, LAW INSIDER, https://www.lawinsider.com/dictionary/warm-transfer (last visited Apr. 27, 2022).

savings comes from." *Id.* at 49:20. Once SaveOnSP assists the patient in enrolling in patient assistance, "it relays that to Accredo, so that it's housed in our system and then again, the claims from there on out just process at $0." *Id.* at 35:54

66. The SaveOnSP Program then causes CarePath to be electronically billed for an inflated copay cost that is not connected to the patient's true out-of-pocket responsibility. The amount charged to the CarePath card at the point of sale is communicated using an "OCC-8" code, which tells JJHCS that the patient owes a copay for the drug. That code is supposed to communicate the patient's true out-of-pocket responsibility as set by their health plan. Instead, SaveOnSP causes an inflated charge to be communicated to JJHCS for the express purpose of draining more patient assistant funds from the patient's CarePath card.

67. This misrepresentation of an inflated copay is made to JJHCS even as it admits elsewhere that patients in the SaveOnSP Program do not have any copay obligation whatsoever. *See Pay $0 for Select Specialty Medications*, *supra* ¶ 11 ("If [a patient] participates in SaveOnSP, he won't pay anything ($0) out-of-pocket.").

68. Finally, SaveOnSP charges the payer "25% of the savings that's achieved." *SaveOnSP IPBC Video*, *supra* ¶ 9, at 37:38. To facilitate this payment, payers sign "a 25% joinder agreement," which "allows Express Scripts to bill you for that fee on your administrative invoice. So you'll see a simple line item for SaveOnSP." *Id.* at 40:50. In other words, SaveOnSP is paid a percentage of the "savings" it has achieved for payers by meeting the payer's obligations to the patient with patient assistance funds—assistance that SaveOnSP obtains by inducing patients to violate the terms and conditions of CarePath.

69. SaveOnSP also admits to engaging in careful tactics designed not for the patient's benefit but to optimize earnings. For example, in deciding which drugs make it onto

SaveOnSP's drug list, the representative explains that SaveOnSP looks to which drugs "have the most lucrative copay assistance programs" and that SaveOnSP may "remove drugs from the programs" if "something comes to our attention where the funding goes away completely." *Id.* at 14:47. This further demonstrates that SaveOnSP is making business-driven decisions without any regard for what is best for the patients. Indeed, while SaveOnSP promises patients that they will receive their medication for $0, if the patient assistance is removed, it will eventually move the drug out of the SaveOnSP Program: "we would honor the copay assistance or the $0 SaveOn copay until they were able to effectively manage that patient out, manage that drug out." *Id.* at 14:58.

70. In order to ensure that only the most lucrative drugs are on its list, SaveOnSP monitors manufacturers' assistance terms and conditions: "in the event that pharma decides to pull back funding for their programs ***or decides to change the terms of the program***, it's seamless to the member. ***SaveOn is actively watching*** these claims process and sees when any of these changes occur." *Id.* at 31:50. And in response to such a change, SaveOnSP might switch one drug off their list in exchange for another one: "it might be a prompt to determine, 'Do we need to make a change in the drug list for this program? Because we are not saving as much as we initially anticipated, and there's another drug where we could.'" *Id.* at 32:09.

71. Likewise, to minimize the necessary coverage and maximize profits, payers using the SaveOnSP Program are encouraged to pick the state EHB-benchmark plan that has the lowest number of requirements: "So again, the ACA defines the essential by again, leveraging a state benchmark. You do not have to leverage your own current state or the state in which most of your members reside. It's simply a guideline for how to administer that essential health benefit. So for example, many commercial plans pick Utah because it had the fewest number of

required drugs to cover, and therefore it was the most cost-effective. So all we're saying is that Utah is setting the list of drugs or the number of drugs by therapeutic category to be deemed essential." *Id.* at 22:40. In other words, instead of picking a state benchmark that reflects where a payer's patients live or where the drug coverage is most comprehensive, SaveOnSP encourages payers to choose a state benchmark with as few requirements as possible to maximize profits.

72. The SaveOnSP Program representative also admits that the SaveOnSP Program operates in a legal "gray area" as it relates to "qualified high deductible HSA [i.e., Health Savings Account] plan[s]." *Id.* at 25:55; 26:27. The representative acknowledges in her presentation that "copay assistance is not ACA compliant in an HSA plan." *Id.* at 26:43. But she explains that SaveOnSP gets away with knowingly breaking this rule because of a lack of oversight: "there's no requirement that patients provide documentation or confirm that they've met their deductibles before they get copay assistance," and "there's no governing body that's really monitoring the industry today," so "copay assistance happens in qualified HSA plans all the time." *Id.* at 26:50. It thus leaves it to plans to "determine whether or not it's appropriate to include their HSA plans in the SaveOn offering or not." *Id.* at 27:27.

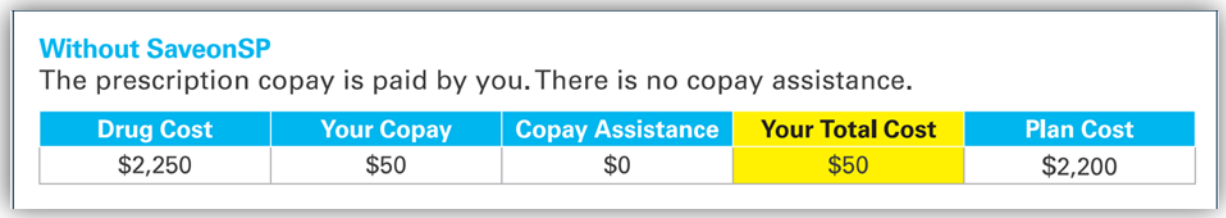
73. Further, SaveOnSP deceives manufacturers by actively concealing its role and interference with patient assistance programs. SaveOnSP knows that such programs often have a requirement that a patient pay $5 or $10 of the cost of the prescription. But SaveOnSP intentionally circumvents this requirement by shifting that $5 or $10 obligation onto the payer—and actively conceals from JJCHS that it has done so by using the artifice of a "tertiary biller," which is "really SaveOn behind the scenes." *Id.* at 30:24.

74. While SaveOnSP engages in these wrongful courses of conduct to increase profits, it unfortunately comes at a great cost to patients. Patient assistance programs are meant

to help patients pay their actual and required out-of-pocket costs. By changing the amounts owed by patients based on only the availability of patient assistance, the programs disconnect patient assistance from actual cost to patients, causing patient assistance programs to be more expensive than originally intended, and converting what is meant to be patient assistance into a manufacturer subsidy for SaveOnSP and its partners. *See The Patient Impact of Manufacturing Copay Assistance in an Era of Rising Out-of-Pocket*, *supra* ¶ 33, at 17 (explaining that "accumulator adjustment and maximizer programs . . . counteract the uptake of manufacturer copay assistance shifting the cost burden back onto patients" and that "limiting [patients' use of copay assistance programs] without giving patients a new way to address their affordability issues will negatively impact patients"). By these actions, SaveOnSP wrongly increases the costs of patient assistance programs and, unless enjoined, will make it untenable for such programs to continue to be provided.

75. Moreover, SaveOnSP misleads patients about the nature of the SaveOnSP Program. SaveOnSP does not tell patients that by enrolling in the SaveOnSP Program, they are breaching their agreement with JJHCS. It does not tell patients that the SaveOnSP Program may cause as much as a year's worth of patient assistance to be drained in just a few prescription fills. And it does not tell patients that it charges a fee of at least 25% of the patient assistance funds pulled.

76. It also does not tell patients that patient assistance is available without the SaveOnSP Program. Indeed, in marketing materials, SaveOnSP misrepresents to patients that "Without SaveonSP," "[t]here is no copay assistance":



Without SaveonSP

The prescription copay is paid by you. There is no copay assistance.

Drug Cost	Your Copay	Copay Assistance	Your Total Cost	Plan Cost
$2,250	$50	$0	$50	$2,200

SaveonSP: Copay Offset Program for Specialty Medication, BLUECROSS BLUESHIELD OF WESTERN NEW YORK, https://www.bcbswny.com/content/dam/BCBSWNY/broker-group/public/pdf/group/computer-task-group/Saveon-Member-Flyer.pdf (last visited Apr. 27, 2022). This is false: manufacturers provide copay assistance independently of SaveOnSP, and did so for many years before SaveOnSP ever began interfering in these programs.

77. Further, the SaveOnSP Program puts patients who decide not to enroll in an even more precarious scenario: They will still have an inflated copay obligation, but the payer does not cover the cost, and the patient is told that he or she will have to pay the cost alone. *Id.*

78. Finally, in either case, no payments count towards the patient's deductible or out-of-pocket maximum, so the patient will still face higher costs for other healthcare services (such as doctor's visits or diagnostic testing). *Pay $0 for Select Specialty Medications*, *supra* ¶ 11. The marketing materials for the SaveOnSP Program referenced in paragraph 11 above make this clear, noting that in either scenario, payments made for the drug "won't count towards [the patient's] deductible or out-of-pocket maximum." *Id.*

79. The federal government has recognized that assistance from manufacturers is for patients, not payers, and has explained patients are harmed when payers "shift costs back to the patient prematurely by not applying the full value of the manufacturer-sponsored assistance to a patient's health plan deductible." *See* Medicaid Program, 85 Fed. Reg. 87,000, 87,049 (Dec. 31, 2020) (codified at 42 C.F.R pts. 433, 438, 447, and 456). Indeed, CMS has even issued a

rule intended to ensure that patient assistance benefits patients, not payers, 85 Fed. Reg. at 87,048–58, and has explained that the rule exists because "[h]ealth plans, with the help of third-party pharmacy benefits administrators, often reap the benefits of [patient assistance] by declining to allow [it] to offset patients' out-of-pocket costs," and as a result "plans are enriched through the reduction in the amount they have to cover for these drugs." *See Pharm. Research & Mfs. of Am. v. Becerra*, No. 21-CV-01395, Dkt. 32-1, at 1 (D.D.C. Feb. 3, 2022).

80. Payers already can and do negotiate pricing discounts with manufacturers, including by securing rebates that manufacturers pay after patients fill prescriptions. *See The 2021 Janssen U.S. Transparency Report*, *supra* ¶ 25, at 6 (indicating that since 2016, "the rebates, discounts and fees we have provided to commercial insurers and PBMs have increased almost fivefold" and that Janssen provided $8.3 billion in rebates, discounts, and fees to commercial insurers and PBMs in 2021); *see also Form 10-K*, *supra* ¶ 25, at 37 (Cigna stating, "[w]e maintain relationships with numerous pharmaceutical manufacturers, which provide us with, among other things: . . . discounts, in the form of rebates, for drug utilization"). In fact, SaveOnSP has inflated patients' drug copay obligations even as JJHCS has consistently decreased the price of the drugs targeted by the SaveOnSP Program. *See The 2021 Janssen U.S. Transparency Report*, *supra* ¶ 25, at 2 (indicating that "net prices for Janssen medicines have declined for the fifth year in a row," including a net decline of -2.8% in 2021 (compared to the 2021 consumer inflation rate of 7%)).

81. Patient assistance does not exist as additional funding for payers to absorb on top of those enormous price concessions. But various publicly available materials describing the SaveOnSP Program explicitly acknowledge that the program is designed for just that: to enrich payers.

82. For example, in a presentation given to the New Jersey Health Insurance Fund, a New Jersey-based insurance pool, the SaveOnSP Program is described as a "very aggressive program" that sets copays to "maximize manufacturer assistance dollars" so that "***plan sponsor spend*** [is] reduced $2.50 - $4.50 [per member per month]." Joseph M. DiBella, *New Jersey Health Insurance Fund*, PERMA (Nov. 2019) at 19–20, https://slideplayer.com/slide/17742625/ (emphasis added).

83. Similarly, an agenda for the Burlington County Insurance Commission, another New Jersey-based insurance pool, notes that the SaveOnSP Program is being implemented "***so that the plan can maximize manufacturer assistance*** dollars (coupons) while reducing the member's copay to $0." *Meeting and Reports*, BURLINGTON CNTY. INS. COMM'N (Nov. 5, 2020), at 28, https://bcnj.co.burlington.nj.us/Upload/BCIC/Images/Agenda_11-5-20.pdf (emphasis added).

84. And in another agenda for Southern Skyland Regional, a New Jersey-based insurance fund, there are notes that while "Members receive a $0 copay," the "***plan receives the remaining discount***." *Agenda & Reports*, Southern Skyland Regional (Oct. 5, 2021), at 8, https://static1.squarespace.com/static/5b1c2db85ffd2031c58b5583/t/615db86e5abc5715e41a709e/1633532015317/A_SSRHIF_October+5th+Agenda.pdf (emphasis added).

85. SaveOnSP's own website emphasizes the same, explaining how "plan[s] see savings generated" from its program. *See Frequently Asked Questions*, SAVEONSP, https://www.saveonsp.com/employers/ (last visited Apr. 27, 2022); *see also Copay Assistance Strategy Reduces Financial Burdens for Plans and Patients*, *supra* ¶ 23 (highlighting that "[i]n 2020, plans that participated in these copay assistance solutions [like the SaveOnSP Program] experienced a specialty trend of -7.2%, while nonparticipating plans experienced an 8.7%

specialty trend."); *Form 10-K*, *supra* ¶ 25, at 7 (Cigna stating that it has a "partnership with SaveOnSP," an "aggressive solution" that "adapts" to changes in manufacturer programs to "protect plan design preferences and achieve lower trend" for health plans).

86. And while these materials also tout reduced costs to patients, they mislead patients by obscuring the fact that patients can get the benefit of reduced costs by directly signing up for manufacturer assistance, without any involvement from SaveOnSP whatsoever.

87. Further underscoring that the SaveOnSP Program is for the benefit of payers and not patients, SaveOnSP Program materials show that even when patients do hit their deductible or out-of-pocket maximum through other means, SaveOnSP will continue to extract patient assistance. *See Copay Assistance Program & Solutions*, *supra* ¶ 12, at 5 ("[T]he member continues to max out the copay assistance throughout the plan year regardless of whether they hit their DED/MOOP through other means.").

88. Finally, the SaveOnSP Program also burdens patients with a complicated enrollment process that can create unnecessary confusion for individuals already under pressure from difficult medical circumstances. *See* Anndi McAfee, *SaveonSP's Copay Maximizer Failed Me: A Patient's Perspective*, DRUG CHANNELS (Nov. 13, 2020), https://www.drugchannels.net/2020/11/saveonsps-copay-maximizer-failed-me.html ("If SaveonSP had not used all of my money, I probably would have continued on in sweet blissful ignorance. But here I am again, expending precious time and energy to ensure that my drug gets into my body."). As noted in paragraph 13 above, one step in the SaveOnSP Program is to falsely tell a patient who is entitled to insurance coverage for a life-saving medication that their request for coverage was denied, as a ruse to push the person to apply for copay support just to drive greater profitability for SaveOnSP. *Human Resources Committee Meeting*, *supra* ¶ 12, at 69.

IV. JJHCS Is Harmed by SaveOnSP's Abusive Practices

89. CarePath's terms and conditions typically require patients to pay $5 or $10 when using the Assistance Program, and they preclude patients from using the Assistance Program with "any other coupon, discount, prescription savings card, free trial, or other offer." *See, e.g.*, DARZALEX® Savings Program, *supra* ¶ 18.

90. The SaveOnSP Program is clearly such an "offer." Indeed, the SaveOnSP representative refers to the SaveOnSP Program in her presentation as the "SaveOn ***offering***." *SaveOnSP IPBC Video*, *supra* ¶ 9, at 4:25; 27:31. And marketing materials similarly state, "That's why your plan ***offers*** a program called SaveOnSP, which can help lower your out-of-pocket costs to $0." *See Pay $0 for Select Specialty Medications*, *supra* ¶ 11 (emphasis added). Nevertheless, despite its knowledge of these terms, SaveOnSP implements its program to extract CarePath's funds.

91. SaveOnSP's conduct is clear from its publicly available drug lists. For example, one such list includes 14 Janssen drugs: BALVERSA®, DARZALEX®, DARZALEX FASPRO®, ERLEADA®, IMBRUVICA®, OPSUMIT®, REMICADE®, RYBREVANT®, SIMPONI®, STELARA®, TRACLEER®, TREMFYA®, UPTRAVI®, and ZYTIGA®. *See 2022 SaveOnSP Drug List*, CHRISTIAN BROTHERS EBT, (Dec. 20, 2021), https://www.saveonsp.com/wp-content/uploads/2021/12/cbservices.pdf.

92. Internal JJHCS data concerning CarePath use confirms that SaveOnSP is abusing CarePath. For instance, in 2021, the average amount of CarePath funds pulled per fill for STELARA® patients who were not enrolled in the SaveOnSP Program was $1,171, while the average amount of CarePath funds pulled per fill for STELARA® patients who were enrolled in the SaveOnSP Program was $4,301.

93. The same pattern holds true for patients on TREMFYA®. In 2021, the average amount of CarePath funds pulled per fill for TREMFYA® patients who were not enrolled in the SaveOnSP Program was $1,126, while the average amount of CarePath funds pulled per fill for TREMFYA® patients who were enrolled in the SaveOnSP Program was $3,717.

94. The difference is even starker for other drugs. For example, the average amount of CarePath funds pulled per fill for UPTRAVI® patients who were not enrolled in the SaveOnSP Program was only $418, while the average amount of CarePath funds pulled per fill for UPTRAVI® patients who were enrolled in the SaveOnSP Program was $5,000.

95. These trends continue into this year. For January through March of 2022, the average amount of CarePath funds pulled per fill for STELARA® patients who were not enrolled in the SaveOnSP Program was $2,057, while the average amount of CarePath funds pulled per fill for STELARA® patients who were enrolled in the SaveOnSP Program was $6,401.

96. Likewise, for the same time period, the average amount of CarePath funds pulled per fill for TREMFYA® patients who were not enrolled in the SaveOnSP Program was $1,796, while the average amount of CarePath funds pulled per fill for TREMFYA® patients who were enrolled in the SaveOnSP Program was $3,745.

97. And, for the same time period, the average amount of CarePath funds pulled per fill for UPTRAVI® patients who were not enrolled in the SaveOnSP Program was only $1,242, while the average amount of CarePath funds pulled per fill for UPTRAVI® patients who were enrolled in the SaveOnSP Program was $6,979.

98. SaveOnSP harms JJHCS not only by causing inflated amounts of patient assistance to be charged per fill, but also by causing greater amounts of patient assistance to be charged earlier in the year. Many patients do not stay on therapy for an entire year. Thus, when SaveOnSP seizes a year's worth of copay assistance by repeatedly charging inflated copays, but the patient does not actually fill a year's worth of prescriptions, SaveOnSP reaps an additional windfall and charges JJHCS for more copay assistance than is actually warranted. In some instances, SaveOnSP has extracted an entire year's worth of patient assistance by the middle of the year.

99. Indeed, SaveOnSP causes JJHCS to pay out the maximum amount of funds available per patient far more often than it otherwise would. For example, in 2021, only 3% of STELARA® patients who were not enrolled in the SaveOnSP Program exhausted the full CarePath benefit of $20,000, while ***33%*** of STELARA® patients who were enrolled in the SaveOnSP Program exhausted the full CarePath benefit of $20,000.

100. Through the SaveOnSP Program, SaveOnSP knowingly and wrongfully harms JJHCS by causing it to pay CarePath funds solely for its own enrichment. JJHCS provides CarePath funds to help patients bridge the gap between what they must pay out-of-pocket to obtain their Janssen drugs and what they can afford. But the SaveOnSP Program interferes with this intended purpose by causing JJHCS to pay out exponentially more CarePath funds per patient only so that it may profit in violation of the CarePath terms and conditions.

101. Further, there is no easy or foolproof way for JJHCS to simply reduce the amount of assistance it provides to all patients enrolled in SaveOnSP's Program. This is because SaveOnSP has taken steps to obscure when funds are being extracted from CarePath through its Program, including recently by varying the patient's out-of-pocket obligation per prescription

fill, such that the amounts extracted from the copay card by the pharmacy are not consistent and easily detectible. Further, JJHCS cannot reduce cost support preemptively to prevent SaveOnSP's activities without an unacceptable risk that individual patients may be misidentified and suffer from reduced cost support and consequently be unable to afford their therapy. The secretive nature of SaveOnSP's operations, therefore, renders any attempt to reduce copay assistance on a patient-by-patient basis unworkable as it risks harming the very patients CarePath was designed to support.

102. For STELARA® and TREMFYA®, JJHCS released a new version of the terms and conditions that were publicly on the CarePath website in December 2021. *See* STELARA® Savings Program (Dec. 2021), https://www.janssencarepath.com/sites/www.janssencarepath-v1.com/files/stelara-savings-program-overview.pdf?v=39; TREMFYA® Savings Program (Dec. 2021), https://www.janssencarepath.com/sites/www.janssencarepath-v1.com/files/tremfya-savings-program-overview.pdf?v=88.

103. The new terms and conditions specify explicitly that to be eligible for CarePath, "you . . . must pay an out-of-pocket cost for your medication." *Id.* They also explicitly prohibit use of programs like SaveOnSP, stating "Patients who are members of health plans that claim to eliminate their out-of-pocket costs are not eligible for cost support." *Id.*

104. To this date, however, SaveOnSP has not taken Janssen's drugs off its list, and continues to induce patients in the SaveOnSP Program to sign up for CarePath in violation of CarePath's terms and conditions.

105. Thus, SaveOnSP continues to harm JJHCS, entitling it to relief. Moreover, damages for ongoing and future wrongdoing are inadequate because SaveOnSP takes concerted

measures to avoid detection. Unless enjoined, it will continue to cause damages and irreparable harm to JJHCS.

COUNT I:
TORTIOUS INTERFERENCE WITH CONTRACT

106. JJHCS re-alleges paragraphs 1–105 as if fully set forth herein.

107. JJHCS has a valid and enforceable contract with the patients who use CarePath.

108. The CarePath terms and conditions prohibit patients from being enrolled in SaveOnSP while using CarePath.

109. SaveOnSP knowingly and wrongfully induces patients to agree to CarePath's terms and conditions, thereby intentionally causing those patients to breach their contract with JJHCS every time they use CarePath funds while enrolled in the SaveOnSP Program.

110. Through its wrongful inducement, SaveOnSP knowingly and proximately causes JJHCS damage by making it pay more money from CarePath than it otherwise would have for a purpose JJHCS did not intend.

111. SaveOnSP has therefore tortiously interfered with JJHCS's agreement with patients who use CarePath.

COUNT II:
DECEPTIVE TRADE PRACTICES
IN VIOLATION OF N.Y. GEN. BUS. LAW § 349

112. JJHCS re-alleges paragraphs 1–111 as if fully set forth herein.

113. SaveOnSP has been and is engaging in willful deceptive acts and practices in New York against JJHCS and the public in the conduct of its business through the following consumer-oriented acts: engineering a false denial of coverage at the point of sale to coerce patients into enrolling in the SaveOnSP Program; telling patients that there is "no copay

assistance with SaveOnSP" when manufacturers do in fact provide assistance independently of the SaveOnSP Program; failing to tell patients that by enrolling in the SaveOnSP Program, they are breaching their agreement with JJHCS; and failing to tell patients that they charge a fee of at least 25% of the patient assistance funds extracted from JJHCS.

114. Through its willful deceptive acts and practices, SaveOnSP causes damage to the public, including patients, by causing undue stress and confusion through acts such as engineering false denials of coverage; jeopardizing the viability of patient assistance programs like CarePath by making them prohibitively expensive; and making other patient healthcare needs more expensive by not counting any of the funds spent on patients' medication towards their ACA maximum or deductible.

115. Through its willful deceptive acts and practices, SaveOnSP also causes damage to JJHCS by making it pay more money from CarePath than it otherwise would have for a purpose JJHCS did not intend.

116. SaveOnSP has therefore violated N.Y. Gen. Bus. Law § 349.

117. SaveOnSP's violation of § 349 also warrants the recovery of attorneys' fees.

DEMAND FOR JURY TRIAL

118. JJHCS hereby respectfully requests a trial by jury for all claims and issues in its Complaint which are or may be entitled to a jury trial.

PRAYER FOR RELIEF

NOW, THEREFORE, Plaintiff JJHCS respectfully requests that the Court:

A. Award JJHCS damages in an amount to be ascertained at trial.

B. Award to JJHCS pre-judgment and post-judgment interest.

C. Issue an injunction preventing SaveOnSP from implementing the SaveOnSP Program as to Janssen drugs.

D. Award JJHCS its reasonable attorneys' fees.

E. Grant such other and further relief as the Court may deem appropriate.

Respectfully submitted,

SILLS CUMMIS & GROSS P.C.
One Riverfront Plaza
Newark, New Jersey 07102
(973) 643-7000

By: s/ Jeffrey J. Greenbaum
JEFFREY J. GREENBAUM
KATHERINE M. LIEB

PATTERSON BELKNAP WEBB & TYLER LLP
Adeel A. Mangi
Harry Sandick (*pro hac vice* forthcoming)
George LoBiondo
1133 Avenue of the Americas
New York, New York 10036
(212) 336-2000

Attorneys for Plaintiff
Johnson & Johnson Health Care Systems Inc.

Dated: May 4, 2022

CERTIFICATION PURSUANT TO LOCAL CIVIL RULE 11.2

Pursuant to Local Civ. Rule 11.2, I hereby certify to the best of my knowledge, information and belief that the matter in controversy is not the subject of any other action pending in any court, or of any pending arbitration or administrative proceeding.

I certify that the foregoing statements made by me are true. I am aware that if any of the foregoing statements made by me are willfully false, I am subject to punishment.

Respectfully submitted,

SILLS CUMMIS & GROSS P.C.
One Riverfront Plaza
Newark, New Jersey 07102
(973) 643-7000

By: s/ Jeffrey J. Greenbaum
JEFFREY J. GREENBAUM
KATHERINE M. LIEB

PATTERSON BELKNAP WEBB & TYLER LLP
Adeel A. Mangi
Harry Sandick (*pro hac vice* forthcoming)
George LoBiondo
1133 Avenue of the Americas
New York, New York 10036
(212) 336-2000

Attorneys for Plaintiff
Johnson & Johnson Health Care Systems Inc.

Dated: May 4, 2022